

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75-271

CHEMISTRY REVIEW(S)

Chemistry Closed

1. CHEMIST'S REVIEW #4

2. ANDA 75-271

3. APPLICANT, Name/Address/Telephone/Fax:

Zenith Goldline Pharmaceuticals
Attention: Jason A. Gross
140 Legrand Avenue
Northvale, NJ 07647
Tel# (210) 767-1700. FAX# (800) 631-1583

US authorized agent for:
Steripak Limited, UK
(wholly owned subsidiaries of IVAX Corp)

4. LEGAL BASIS FOR ANDA SUBMISSION: 505(j)

5. SUPPLEMENT: - n/a

6. PROPRIETARY NAME: none

7. Non-PROPRIETARY NAME: Cromolyn Sodium Inhalation Solution
USP, 1.0%
Innovator's Product Name: Intal® Nebulizer Solution; Rhone
Poulenc Rorer (formerly Fisons Ltd.)

8. Supplement Provides For: n/a

9. AMENDMENTS & OTHER DATES.

FIRM:

12-11-97 original submission
01-08-98 New Correspondence (filing issues)
08-26-98 ANDA Amendment; Chemistry
10-09-98 new correspondence (micro issues).
12-30-98 labeling amendment
03-09-99 New Correspondence; Request for meeting.
04-12-99 New Correspondence; Minutes of meeting.
06-24-99 ANDA Amendment; Chemistry
07-29-99 Micro Amendment
11-15-99 Gratuitous Chemistry Amendment
12-01-99 ANDA FAX Amendment; Chemistry

FDA:

01-20-98 Receipt of ANDA
02-18-98 Labeling Review (N/A)
04-02-98 Per DBE, bioeq. acceptable
07-01-98 N/A MAJOR Amendment/CR #1
03-03-99 Labeling Review (N/A)

03-08-99 N/A MAJOR-Amendment/CR #2
07-15-99 Micro Review #1 (deficient).
11-22-99 Chemistry NA #3 (FAX Amendment request)

OTHER:

01-20-98 EER submitted
04-12-98 Micro Review (ONDC); N/A
04-12-99 N/A (micro issues)
07-15-99 Method Verification; LA District Lab; Adequate.
11-12-99 EER Acceptable for listed firms.

10. **PHARMACOLOGICAL CATEGORY:** Prophylactic agent indicated in the management of patients with bronchial asthma.

11. **Rx or OTC:** Rx
12. **RELATED ANDA's:** n/a
13. **DOSAGE Form:** solution
14. **POTENCY:** 20 mg/2 mL
15. **CHEMICAL Name:** see USP 23
16. **Records & Reports:** n/a

17. **COMMENTS.**

A. General Comments:

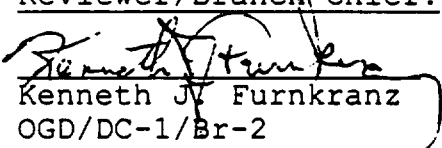
1. The drug substance and drug product are USP items.
2. The Bio review is acceptable 04-02-98.
3. The 7/29/99 Micro Amendment will need to be reviewed.

B. Comments to the Applicant's Amendment

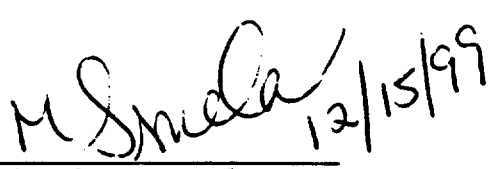
1. Steripak has demonstrated that the laminated foil pouch adequately protects, and does not itself contaminate the drug product.

18. **CONCLUSIONS & RECOMMENDATIONS:** Chemistry Closed. Pending micro review and submission of FPL.

19. **Reviewer/Branch Chief:**


Kenneth J. Furnkranz
OGD/DC-1/Br-2

Date Started: 12/9/99


Michael J. Smela, Jr.
OGD/DC-1/Br-2; T/L

Labeling amendment of 12/17/99 is acceptable
per TW 1/12/99. Micro is acceptable per
Stinebaugh on 12/21/99. ANDA may be approved.
M. Smela 1/5/00

Date Completed: 12/13/99

Page(s) 9

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Commercial/Confidential

Information and are not

releasable.

Chem Rev 4

12/13/99

1. CHEMIST'S REVIEW #32. ANDA 75-2713. APPLICANT, Name/Address/Telephone/Fax:

Zenith Goldline Pharmaceuticals
 Attention: Jason A. Gross
 140 Legrand Avenue
 Northvale, NJ 07647
 Tel# (210) 767-1700. FAX# (800) 631-1583

US authorized agent for:
 Steripak Limited, UK
 (wholly owned subsidiaries of IVAX Corp)

4. LEGAL BASIS FOR ANDA SUBMISSION: 505(j)5. SUPPLEMENT: n/a6. PROPRIETARY NAME: none7. Non-PROPRIETARY NAME: Cromolyn Sodium Inhalation Solution USP, 1.0%

Innovator's Product Name: Intal® Nebulizer Solution;
 Rhone Poulenc Rorer (formerly
 Fisons Ltd.

8. Supplement Provides For: n/a9. AMENDMENTS & OTHER DATES.A. FIRM:

12-11-97 original submission
 01-08-98 New Correspondence (filing issues)
 08-26-98 ANDA Amendment; Chemistry
 10-09-98 new correspondence (micro issues).
 12-30-98 labeling amendment
 03-09-99 New Correspondence; Request for meeting.
 04-12-99 New Correspondence; Minutes of meeting.
 06-24-99 ANDA Amendment; Chemistry
 07-29-99 Micro Amendment

B. FDA:

01-20-98 Receipt of ANDA
 02-18-98 Labeling Review (N/A)
 04-02-98 Per DBE, bioeq. acceptable
 07-01-98 N/A MAJOR Amendment/CR #1
 03-03-99 Labeling Review (N/A)
 03-08-99 N/A MAJOR Amendment/CR #2

07-15-99 Micro Review #1 (deficient).

OTHER:

01-20-98 EER submitted

04-12-98 Micro Review (ONDC); N/A

04-12-99 N/A (micro issues)

07-15-99 Method Verification; LA District Lab; Adequate.

10. PHARMACOLOGICAL CATEGORY: Prophylactic agent indicated in the management of patients with bronchial asthma.

11. Rx or OTC: Rx

12. RELATED ANDA's: n/a

13. DOSAGE Form: solution

14. POTENCY: 20 mg/2 mL

15. CHEMICAL Name: see USP 23

16. Records & Reports: n/a

17. COMMENTS.

A. General Comments:

1. The drug substance and drug product are USP items.
2. The drug product is a sterile aqueous solution.
3. The Bio review is acceptable 04-02-98.
4. Micro review has not yet been completed for this sterile solution.
5. Unipak inspection necessary.

B. Comments to the Applicant's Amendment

1. Steripak must demonstrate that the laminated foil pouch protects, but does not contaminate the drug product.

18. CONCLUSIONS & RECOMMENDATIONS: N/A

19. Reviewer/Branch Chief:

Kenneth J. Furnkranz
OGD/DC-1/Br-2

Michael J. Smela, Jr.
OGD/DC-1/Br-2; T/L

Date Started: 10/25/99

Date Completed: 11/5/99

Date Revised: 11/15/99

Page(s)

10

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Item Rev 3

11/5/99